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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,276	09/07/2000	Dominique P. Bridon	REDC-2111 USA	9972

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EXAMINER	
WELLS, LAUREN Q	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/657,276	BRIDON ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-9,12-17 and 21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9,12-17 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 7-9, 11-17, and 21-25 are pending. The Amendment filed 9/25/02, Paper No. 15, cancelled claims 1-5, and amended claims 7 and 15.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 9/25/02 (Paper No. 15) to the rejection of claims 1-5, 7-9, 11-17, 21-25 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's amendment and arguments are sufficient-in-part to overcome the 35 USC 112, second paragraph, rejections in the previous Office Action. See below for details.

The Applicant's arguments are sufficient to overcome the 35 USC 112, first paragraph, rejection in the previous Office Action.

112 Rejection Maintained

The rejection of claims 16 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 4/30/02, Paper No. 12, and those found below.

(i) The rejection of the phrases "therapeutically active region and "less therapeutically active region" is maintained. Applicant argues, "nearly two pages of the specification are dedicated to listing therapeutic peptides that are well-known in the art. . .Consequently, it is standard practice to initially make modification and/or mutation to a peptide as far as possible from the therapeutically active region, to minimize negative effects on the therapeutically active portion thereof". This argument is not persuasive, as these terms are relative. What is considered active or less active in one case, may not be so in another case. Applicant argues, "The 'less therapeutically active region' is defined as the region' located away from the

'therapeutically active region, such that the modification at the less therapeutically active region does not substantially affect the therapeutic activity of the therapeutic peptide". This argument is not persuasive. Since the therapeutically active region is relative, so is that which is defined by its presence.

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The rejection of claims 7-9, 11-17 and 21-25 under 35 U.S.C. 103(a) as being unpatentable over Pouletty et al. (WO 95/10302) in view of Oppenhelm et al. (5,837,247) is MAINTAINED for the reasons set forth in the Office Action mailed 4/3/02, Paper No. 12, and those found below.

Applicant argues, "Pouletty et al. fails to mention protecting a peptide from peptidase degradation or binding a peptide in a less therapeutic region". This argument is not persuasive. First, the Examiner respectfully points out that the recitation "for protecting from peptidase degradation a therapeutic peptide sensitive to such peptidase degradation" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, since Pouletty et al. teach the same method steps as that of the instant invention, their method must have the property of protecting from peptidase degradation a therapeutic peptide sensitive to such peptidase degradation. Regarding the term "less therapeutic region", the Examiner respectfully points out that this term is relative and vague

and indefinite. Furthermore, the Examiner respectfully points out that one of skill, using the teachings of Pouletty et al., would be motivated not to alter the therapeutic region of a protein, as such an alteration may alter is therapeutic affects.

Applicant argues, "In Pouletty et al., the half life is extended because the peptide derivative covalently bonds to blood components. . .This concept is therefore applicable to both peptides susceptible and non-susceptible to peptidase degradation". This argument is not persuasive, as a reference is relied upon for its teachings as a whole, and as argued by Applicant, the reference teaches modifying peptides susceptible to peptidase degradation.

Applicant argues, "it has unexpectedly been found that the coupling of the peptide covalently to a blood components such as serum albumin renders it less susceptible to peptidase degradation in vivo. Pouletty et al. fail to make any mention of protecting peptides against peptidase degradation". This argument is not persuasive. Again, the Examiner respectfully points out that the Pouletty et al. and the instant invention teach the same method steps. Thus, the method of Pouletty et al. must have the property of protecting peptides against peptidase degradation.

Applicant argues, "Pouletty et al. fail to disclose a method of including the step of modifying the peptide at a less therapeutically active region. . .Pouletty et al. fail to teach identifying a therapeutically active region of the peptide". This argument is not persuasive. Regarding the term "less therapeutic region", the Examiner respectfully points out that this term is relative and vague and indefinite. Furthermore, the Examiner respectfully points out that one of skill, using the teachings of Pouletty et al., would be motivated not to alter the therapeutic region of a protein, as such an alteration may alter is therapeutic affects.

Applicant argues, "Oppenhelm et al. fail to mention, suggest or imply that the disclosed defensin peptides may be protected against peptidase degradation. . .Oppenhelm et al. fail to mention, suggest or imply that the disclosed defensin peptides may be chemically modified to form peptidase-stabilized defensin derivatives. Finally, Oppenhelm et al. fail to teach either identifying a therapeutically active region of the peptide, or modifying the less therapeutically active region". This argument is not persuasive. First, the argument is not commensurate in scope with the instant claims, which do not recite defensin proteins. Second, the Examiner respectfully points out that, for reasons of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the protein of Oppenhelm et al. in the method of Pouletty et al.

Applicant argues, "the references fail to teach limitations of dependent claims 14 and 25. Specifically, the Oppenhelm et al. fails to teach that one or more of the amino acids in SEQ ID NO:1032 are synthetic. Pouletty et al. also fails to teach such a modification". This argument is not persuasive. The Examiner respectfully points out that a peptide is a peptide. If it is comprised of the same amino acid series and the same modifications and end groups, the protein, whether synthetic or natural, has the same properties and therefore is the same chemically.

Applicant argues, "First, the Pouletty et al. reference discloses only extending in vivo half-lives". This argument is not persuasive. Again, as pointed out above, the limitations of the preamble are not afforded patentable weight. And, as pointed out above, Pouletty et al. and the instant invention teach the same method, thus the method of Pouletty et al. must have the property of protecting peptides from peptidase degradation.

Applicant argues, "the fact that malignant cells are targets for therapeutic conjugates does not mean that one of skill in the art would modify SED ED NO. 1032". This argument is not persuasive. The Examiner respectfully points out that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. In the instant case, Pouletty et al. teach their invention for extending the in vivo lifetimes of physiologically active agents, such as peptides, and further teach malignant cells as targets for their therapeutic conjugates. Oppenhelm et al. teach SEQ ID NO : 1032 as a therapeutic peptide that targets malignant cells. Thus, one of skill in the art would be motivated to teach SEQ ID NO:1032 as the physiologically active agent of Pouletty et al.

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Regarding, the "Unexpected Results" heading in the previous Office Action, the Examiner respectfully points out that this section was included merely to aid Applicant if she decided to file unexpected results.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
December 10, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER 12/13/02

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